

Exhibit A



Exhibit B



INGREDIENTS: ALMONDS, VEGETABLE OIL (CANOLA, SAFFLOWER AND/OR SUNFLOWER), SUGAR, MODIFIED CORN STARCH, SALT, SOY SAUCE (SOYBEAN, WHEAT, SALT), HORSERADISH, ONION, SPICE, FRACTIONATED COCONUT AND/OR PALM KERNEL OIL, GARLIC, MALTODEXTRIN, YEAST EXTRACT, NATURAL FLAVOR, CITRIC ACID, DISODIUM GUANYLATE AND DISODIUM INOSINATE. PEANUT FREE. MAY CONTAIN OTHER TREE NUTS.

FROM CALIFORNIA

PACKED BY: BLUE DIAMOND GROWERS
SACRAMENTO, CA 95812 U.S.A.

Exhibit C

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Wasabi & Soy Sauce

No reviews [Write a Review](#)

Kosher

When we first heard the idea, we were a little skeptical, too. Then we tried one and tasted the great wasabi kick with a salty, sweet finish and we were hooked.

6 oz. can (Case of twelve)

1 lb. bag (Single bag)

1 lb. bag (Case of six)

1.5 oz. foils (Caddie of twelve)

\$8.89

Qty

+ Add to cart

Nutrition Facts

Ingredients

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Healthy & tasty snacks delivered monthly

Blue Diamond Almonds, Bold Wasabi & Soy Sauce, 16 Ounce by Blue Diamond Almonds

542 customer reviews | 9 answered questions

Amazon's Choice for "blue diamond almonds wasabi"

16 oz

Add-on item Ships with eligible qualifying order over \$25. Details

Price: ~~\$9.32~~ (\$0.58 / Ounce) & **FREE Shipping** on orders over \$25 shipped by Amazon. Details

In Stock. Ships from and sold by Amazon.com. Gift-wrap available.

4 Sizes: 16 Ounce

1.5 Ounce (Pack of 12)	4 Ounce (Pack of 12)	16 Ounce	...
\$10.09 (\$0.84 / Ounce)	\$25.91 (\$2.16 / Ounce)	\$9.32 (\$0.58 / Ounce)	

Want it tomorrow, Sept. 27? Add it to a qualifying order within 2 hrs 8 mins and choose **One-Day Shipping** at checkout. Details

Deliver to New York 10016

Qty: 1

1-Click ordering is not available for this item.

Delivery available via **Gifts**

Get this item with your weekly groceries, delivered as quickly as same day or early next morning.

Other Sellers on Amazon

\$17.08 (\$1.07 / Ounce) • Free Shipping	10 new from \$9.32
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About the product

- Contains 1 - 16 ounce resealable bag
- Cholesterol free
- 6g of protein per serving, 3g fiber, 0g trans fat
- A good source of fiber, Smart Snacking on-the-go
- Great wasabi kick with a salty, sweet finish

Exhibit D

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Inspections, Compliance, Enforcement, and Criminal Investigations

Czimer's Foods, Inc 2/4/11



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

February 4, 2011

WARNING LETTER CHI-03-11

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. Richard J. Czimer, Jr.
Owner
Czimer Foods, Inc.
13136 West 159th Street
Homer Glen, Illinois 60491

Dear Mr. Czimer:

The Food and Drug Administration (FDA) inspected your food processing facility, located at 13136 West 159th Street, Homer Glen, IL, on July 8, July 12, August 25, and September 16, 2010. We found that you have serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and associated regulations. You can find the Act and regulations on FDA's website at www.fda.gov¹.

On July 12, 2010, during the inspection, FDA collected samples of a number of your products, including your Black Bear Burger and your Black Bear Steak products. These products are adulterated within the meaning of Section 402(b)(2) of the Act [21 U.S.C. § 342(b)(2)] in that a valuable constituent (Black Bear) has been omitted from the products and another ingredient has been substituted wholly therefore. Specifically, your Black Bear Burger product was found to contain Elk/Red Deer (*Cervus sp.*) rather than Black Bear (*Ursus americanus*), and your Black Bear Steak product was found to contain Brown Bear (*Ursus arctos*) rather than Black Bear.

Furthermore, your Black Bear Burger and Black Bear Steak products are misbranded within the meaning of Section 403(b) of the Act [21 U.S.C. § 343(b)] in that they are offered for sale under the name "Black Bear Burgers" and "Black Bear Steak" but are in fact Elk/Red Deer (*Cervus sp.*) and Brown Bear (*Ursus arctos*), respectively.

During our inspection, we also found that you have serious violations of the Current Good Manufacturing Practice (CGMP) regulation, Title 21, Code of Federal Regulations, Part 110 (21 CFR 110). Because the food products produced in your facility have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or may have been rendered injurious to health, these products are adulterated within the meaning of section 402(a)(4) of the Act [21 U.S.C. § 342(a)(4)].

During the inspection, our investigators observed the following significant violations of 21 CFR 110:

1. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials did not conform to hygienic practices to the extent necessary to protect against contaminations of food, as required by 21 CFR 110.10(b), including maintaining adequate personal cleanliness [21 CFR 110.10(b)(2)] and washing hands thoroughly to protect against contamination [21 CFR 110.10(b)(3)]. Specifically, an employee removed Ready-To-Eat (RTE) cheese products with his bare hands, from your retail display case, without washing and sanitizing his hands prior to handling the RTE cheese and without wearing gloves. The employee then portioned the cheese products with bare hands for a consumer and placed the RTE cheese product back into the display case.
2. You did not manufacture, package, and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and the contamination of food, as required by 21 CFR 110.80(b)(2). Specifically,
 - You do not have a set thermal process for the smoking of exotic meat slim jims and meat jerky products, and do not monitor the smoking operation for processing time or smoking temperature. Further you do not calibrate the thermometers used in the facility. These conditions and controls are necessary to minimize the potential for growth of microorganisms during the smoking process.
 - You do not monitor the pH or water activity of refrigerated, smoked vacuum packed exotic meat slim jims and meat jerky products. These properties can affect the time and temperature necessary to properly smoke the meat products, which would minimize the potential for growth of microorganisms during the smoking process.
3. Your facility failed to use cleaning compounds and sanitizing agents that are safe and adequate under the conditions of use, as required by 21 CFR 110.35(a). Specifically, your facility used a **(b)(4)** based sanitizer, but the sanitizer was not produced or maintained at the concentration specified on the label, which could render the sanitizer unsafe. An employee twice attempted to mix the sanitizer to the appropriate concentration, and on both attempts the **(b)(4)** concentration was significantly greater than the maximum strength specified on the label.
4. Your facility failed to maintain equipment and utensils in an acceptable condition through appropriate cleaning and sanitizing as necessary, as required by 21 CFR 110.80(b)(1). Specifically, on a day that no meat was being cut, the band saw used to cut and section frozen meat pieces had dried particles of meat scraps on the blade, the handle, and in the grooves of the saw's processing table.

This letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. You should investigate and determine the causes of the violations and take prompt actions to correct the violations to bring your products into compliance. Failure to promptly correct these violations may result in legal action without further notice including seizure and injunction.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Rosemary Sexton, Compliance Officer, at the address above. If you have any questions regarding any issues in this letter, please contact Ms. Sexton at 312-596-4225 or rosemary.sexton@fda.hhs.gov.

Sincerely,

/s/

Scott J. MacIntire
District Director

Page Last Updated: 02/14/2011

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Exhibit E



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

EXECUTIVE DIVISION
SPECIAL COUNSEL

September 9, 2015

Bishop Dr. Truman Berst
Alternative Remedies Health & Herbs
425 Ellsworth Street SW
Albany, Oregon 97302-1100

Re: Misbranding/Adulteration of Devil's Claw Dietary Supplements

Dear Bishop Dr. Berst,

This letter constitutes a demand that Alternative Remedies Health & Herbs cease and desist from the marketing, distribution, or sale of misbranded or adulterated devil's claw dietary supplements. For the reasons set forth below, we advise you to furnish the requested documentation and take immediate steps to identify and compensate any consumers who purchased misbranded or adulterated products.

The dietary supplements industry markets devil's claw—the commercial name for the plant *Harpagophytum procumbens* ("Devil's Claw")—as a purported remedy for arthritis and chronic pain. An independent scientific analysis conducted at the New York Botanical Garden ("NYBG") concluded that your company sold a devil's claw supplement derived, in whole or in part, from a different, cheaper species that is considered less desirable: *Harpagophytum zeyheri* (the "Substitute Plant"). This would violate several provisions of federal and New York law. *See, e.g.*, 21 U.S.C. §§ 331(a), 342-343; N.Y. Agric. & Mkts. Law § 199-a; N.Y. Gen. Bus. Law § 349.

Scientists affiliated with NYBG, a leading botanical research center, used a DNA barcoding technique to identify the relevant plant source for a range of supplements labeled as containing devil's claw or devil's claw extract.¹ The NYBG study revealed widespread substitution and adulteration; of 16 U.S. made devil's claw supplements where the relevant plant

¹ DNA barcoding is a sophisticated genetic technique that relies on short, unique sequences of DNA to identify the source of plant or animal material. To carry out the NYBG study, researchers first identified unique mini-barcodes, specifically focused on the *psbAtrnH* genetic marker, to distinguish between the two *Harpagophytum* species. The study analyzed 23 supplements labeled as containing devil's claw or a devil's claw extract, including both single-ingredient supplements and complex mixtures. Five of the tested supplements were produced by non-U.S. companies and labeled for overseas sale, and are therefore excluded from the results discussed in this letter. Of the 18 supplements labeled for sale in the United States, NYBG extracted identifiable DNA from all but two of the products. (Only one of the two is labeled as an "extract" in the "supplement facts" panel.)

source could be identified—produced by 14 separate companies, including large and small firms—100% were found to contain the Substitute Plant, either alone (81%) or in combination with Devil’s Claw (19%). According to subpoenaed documents, this included a product sold by your company as “Devil’s Claw Root,” Lot No. C0239 (the “Tested Lot”). Your product’s label did not disclose the presence of the Substitute Plant. The NYBG study concluded, however, that your company’s product contained the Substitute Plant, not Devil’s Claw.

Because of the implications for consumers, we are contacting your company prior to publication of the NYBG study. This analysis, however, is far from the first to draw attention to serious quality control and compliance problems in the supplement industry. Nor is it the first red flag indicating fraud, misidentification, or other serious problems in the supply chain for Devil’s Claw, a popular and scarce plant indigenous to the Kalahari Desert; reports of raw material suppliers mixing or replacing dried Devil’s Claw root tubers with the similar-looking dried root tubers of the Substitute Plant—a cheaper plant in the same genus—are common. In this context, the results of the NYBG study are especially troubling; they suggest an industry-wide failure to take necessary steps to comply with law and ensure the accuracy of claims concerning the quality and authenticity of the supplements marketed to consumers.

As a matter of commerce, science, and law, Devil’s Claw (*Harpagophytum procumbens*) and the Substitute Plant (*Harpagophytum zeyheri*) are distinct species:

- Commercially, Devil’s Claw is preferred in virtually all respects, is scarcer, and commands a higher market price. After contacting several suppliers, the Office of the New York Attorney General received price quotes for Devil’s Claw root that were *two- to three-times higher* than a similar quote for the Substitute Plant.
- Scientifically, the two plants are separate species that can be easily distinguished in the wild. Herbalists link the purported therapeutic properties of Devil’s Claw—which are not generally accepted in the medical community or approved by the FDA—to certain naturally-occurring chemical compounds, specifically iridoid glycosides. These chemicals tend to occur naturally in Devil’s Claw at much higher concentrations. They also appear in different ratios in the two plants, and at least one chemically potent phenol glycoside in Devil’s Claw (6-acetylacteoside) is missing from the Substitute Plant. Moreover, supplements derived from the Substitute Plant—even those “standardized” to deliver a promised percentage of certain iridoid glycosides—are also likely to expose users to other chemicals that are either absent from Devil’s Claw or present at lower concentrations.²

² Certain overseas jurisdictions allow the Substitute Plant to be sold as part of the same product as Devil’s Claw. This approach has been criticized in the scientific literature due, in part, to the distinct chemical profiles of the two plants and the lack of evidence that the two are pharmacologically equivalent. See, e.g., Nontobeko P. Mncwangi, et al., *What the devil is in your phytochemistry? Exploring species substitution in Harpagophytum through chemometric modeling of ¹H-NMR and UHPLC-MS datasets*, 106 *Phytochemistry* 104-115 (October 2014) (“[O]ur results clearly demonstrate a phytochemical disparity between the two species which may impact on their biological properties. . . . The chemometric analysis results showed that the two species are not chemically equivalent, particularly, that harpagoside is not always present in *H. zeyheri*, suggesting that the therapeutic outcome may be different, thus they should not be used interchangeably until pharmacological equivalence has been confirmed.”)

- Legally, the 1992 Edition of Herbs of Commerce supplies the list of plants that may be sold in the United States commercially under particular common names. 21 C.F.R. 101.4(h).³ The relevant definition—which was reaffirmed in the more recent edition—defines devil’s claw as *Harpagophytum procumbens*, *i.e.* as Devil’s Claw. Representing any plant other than Devil’s Claw as “devil’s claw” is inconsistent with the definition codified in the Herbs of Commerce and is misleading as a matter of law. Misapplying the common name is all the more problematic where, as here, the scientific name of the non-standard species appears nowhere on the label.

Nor are we convinced that the Substitute Plant would be lawful for sale in New York or elsewhere in the United States under its proper scientific name, *i.e.* as *Harpagophytum zeyheri*. Under federal law, a manufacturer may legally sell a “new dietary ingredient”—or an ingredient that was first marketed in the United States after October 15, 1994—if it was (i) used as a source of food; or (ii) submitted to the federal Food and Drug Administration as part of a new dietary ingredient notification at least 75 days prior to initial sale. *See* 21 U.S.C. § 350b; 21 U.S.C. § 331(a); *see also* FDA Draft Guidance on New Dietary Ingredient Notifications, Docket No. FDA-2011-D-0376 76, Fed. Reg. 39111 (July 5, 2011). First, Devil’s Claw has long been marketed in the United States, including as “grapple” and “harpagophytum root.” We have seen no comparable evidence establishing that the Substitute Plant, *i.e.* *Harpagophytum zeyheri*, was sold in the United States prior to 1994, except as an unwanted adulterant.⁴ Second, the Substitute Plant appears to satisfy neither of the requirements for new dietary ingredients.⁵

In connection with an investigation arising under N.Y. Exec. Law § 63(12), N.Y. Gen. Bus. Law § 349, N.Y. Agric. & Mkts. Law § 8, and other authorities, we therefore request a detailed, written response to this letter within 10 business days. In addition to offering you an opportunity to respond to, or dispute any of the analysis above, we ask that your response cover the topics and incorporate the materials identified in the attached Appendix, including but not limited to:

- The methodology and results of any testing your company performs or has performed by a third party on the Tested Lot to independently verify the results of the NYBG study;
- Your company’s plans for identifying and, where appropriate, recalling any and all non-complying devil’s claw supplements;

³ Herbs of Commerce seeks to avoid confusion in the herbal supplements marketplace by applying “a single common name in trade . . . to only one botanical name.” *Id.* at I (introduction). The common name “devil’s claw” perfectly illustrates the problem. Overseas and in non-commercial settings, that name has been used loosely to refer to numerous species, including the Substitute Plant as well as other wholly unrelated plants like *Pisonia aculeate*, *Proboscidea altheaefolia*, and *Senegalia greggii*.

⁴ To the contrary, various sources dating back many years identify the Substitute Plant as an unwanted adulterant, which was not legally exported internationally until European standards were loosened in 2003.

⁵ Like many traditional herbal supplements, Devil’s Claw may be administered orally, including as a tea. This does not convert it or the Substitute Plant into a source of food for purposes of the new dietary ingredient requirements.

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- (iii) Your company's proposal for identifying and, where appropriate, compensating any defrauded or otherwise harmed consumers; and
- (iv) Any and all new reforms your company will implement to ensure the quality and authenticity of the herbal supplements it manufactures or distributes, including new analytical testing methods.

Notwithstanding this response, we further advise you to preserve and retain any and all documents and communications concerning the subjects addressed in this letter, including but not limited to: (i) the sourcing of ingredients for devil's claw and other herbal dietary supplements; (ii) the measures used to verify the reliability of suppliers of devil's claw and other herbal ingredients; (iii) quality control for devil's claw and other herbal dietary supplements, including awareness of misidentification of herbal products and financially motivated adulteration, with respect to raw materials or finished products; (iv) the labeling and marketing of devil's claw and other herbal supplements; and (v) the manufacturing protocols and testing methods employed to ensure the accuracy of all label and marketing claims relating to the identity, purity, potency, or other characteristics of devil's claw and other herbal supplements.

Please do not hesitate to reach out to our office with any questions or concerns.

Respectfully,



Simon G. Brandler
Senior Advisor & Special Counsel
212-416-6544 / Simon.Brandler@ag.ny.gov

APPENDIX

Request for Additional Documentation and Information

With your response, please furnish the following information or documentation:

- (1) For each shipment of ingredients or products your company received since January 1, 2012 that were purportedly derived, in whole or in part, from Devil's Claw and/or the Substitute Plant (the "DC Ingredients"):
 - a. The name, address, telephone number, email address, and other contact information for the supplier from whom your company obtained the shipment;
 - b. The supplier's descriptions of the content of the shipment, as they appeared on order forms, packing slips, contracts, and other written materials;
 - c. The date your company received the shipment;
 - d. The address where your company received the shipment;
 - e. The form in which the DC Ingredients arrived (e.g. powdered extract, cut-and-dried tubers, powdered whole herbs, etc.);
 - f. The address or addresses of the manufacturing facilities that produced any finished supplements containing the DC Ingredients;
 - g. The volume in kilograms of DC Ingredients received;
 - h. The total price your company paid for the DC Ingredients in the shipment in U.S. dollars; and
 - i. Copies of all product labels (front and back) for all supplements produced using the DC Ingredients in that shipment.
- (2) Copies of all audits, reviews, or other documents or communications prepared by your company or a third party to assess the reliability of any supplier who sold DC Ingredients to your company from January 1, 2012 to the present, and a description of any other verification measures not reflected in such documents and communications;
- (3) Copies of all documents and communications, including but not limited to order forms, contracts, packing slips, contracts, correspondence, or other written or electronic materials, concerning the shipment or shipments of DC Ingredients used in manufacturing the Tested Lot;
- (4) A complete description of the methodology and copies of the results of any testing or analyses your company performed or had performed from January 1, 2012 to the present on DC Ingredients or on finished dietary supplements containing DC Ingredients for identity, potency, purity, or any other characteristic, along with a

statement indicating whether any such testing could distinguish between Devil's Claw and the Substitute Plant;

- (5) A complete description of the testing or other measures your company undertook, is undertaking, or intends to undertake to determine the degree to which the products it sold since January 1, 2012 purporting to contain DC Ingredients were adulterated or misbranded, including but not limited to the Tested Lot;
- (6) The results of any and all testing described in response to Item 5 or of any other testing performed on the Tested Lot;
- (7) Copies of any and all documents or communications concerning the Tested Lot or its sale;
- (8) Copies of all documents and communications your company sent to, received from, or exchanged with any employee or agent of the federal Food and Drug Administration ("FDA") since January 1, 2012 concerning inspections of the company facilities identified in response to Item 1(f) above, including but not limited to Form 483s and your company's response thereto.
- (9) For each year from January 1, 2012 to the present, the total annual revenue or, for 2015, the year-to-date revenue your company received respectively from the sale of dietary supplements containing DC Ingredients in (i) retail sales in New York State; (ii) Internet sales to New York State residents; and (iii) the United States overall;
- (10) A proposal for identifying and, as appropriate, compensating any purchasers of devil's claw supplements your company manufactured who may have received adulterated or misbranded products; and
- (11) A complete description of improvements, safeguards, or reforms your company will implement to avoid adulteration or misbranding of herbal dietary supplements in the future, including but not limited to testing or other measures to detect and prevent the adulteration or misbranding of supplement's containing DC Ingredients.